# III. REVIEW OF SBIR AND STTR APPLICATIONS

## Assignment for Peer Review

SBIR and STTR applications are reviewed three times a year in the NIH Division of Research Grants (DRG). Applications are reviewed by an initial review group or "study section" composed of scientists from both academic and for-profit institutions who meet for one to three days to evaluate grant applications. The study section is organized by a DRG Scientific Review Administrator (SRA).

For the review meeting, each SRA assembles a panel of reviewers according to the mix of applications assigned. Thus, all SBIR and STTR study sections are *ad hoc*, meaning that some members are different from one review meeting to the next. Members are selected for their expertise in the scientific areas of the applications received for that round. This provides for a fair review of a broad range of applications.

***A continually changing roster sometimes is a concern to applicants submitting revised applications. It is likely that many reviewers of an amended application will differ from those of the first review. To provide continuity, the study section has access to prior summary statements.***

SBIR and STTR applicants may include a cover letter that identifies organizations or individuals who **should not** review their applications because of potential conflict of interest. The list should be limited in length and identify the reasons for your objections to specific reviewers. ***This strategy may be particularly useful when you submit a revised application and you believe there is a problem with a reviewer from the previous review.***

## Assignment to an Institute or Center

SBIR and STTR study sections review proposals that fit the missions of more than one NIH Institute or Center (IC). Based on referral guidelines, a DRG referral officer makes a primary funding assignment for each application to one of the ICs. The referral officer may also make secondary assignments to other ICs that may be interested in funding the application.

Applicants can request appropriate primary and secondary assignments. The competition for funding often varies among ICs, and assignment choices may determine whether your application is funded.

## At the Peer Review Meeting

Several weeks before the study section meets, the SRA sends each study section member a copy of the applications to be reviewed.

Usually, the SRA assigns at least two study section members to be the reviewers and to write critiques prior to the meeting. The SRA will also ask one or more members to serve as readers, who identify strengths and weaknesses of applications. Other members of the study section may or may not read the application prior to the review. However, the discussion usually involves many more reviewers than those assigned to it.

Following the discussion of an application's strengths and weaknesses, the committee determines if it has serious deficiencies that would make it unfundable regardless of score. If so, the application is classified as "Not Recommended for Further Consideration, NRFC." These applications are often said to be "NERF'ed."

Applications are NERF'ed if any of the following are deficient: innovative research ideas, focused research plan, sound experimental approach, objective goals accomplishable during six months of Phase I, sufficient experimental detail, knowledge of published relevant work, demonstrated experience in essential methodology, preliminary data indicating high probability of success, acceptable scientific rationale, and plans for Phase II and commercialization.

***NERF'ed applications may be revised and resubmitted. Read the critiques carefully and pay careful attention to the potential reasons for the NERF assignment. Discuss your application with your Program Officer. Revised NERF'ed application can and do receive fundable scores.***

## How Priority Scores Are Determined

If your application warrants a full review, the primary reviewers present their critiques, and readers add their remarks. The reviewers and readers indicate their level of enthusiasm by suggesting a priority score where 1.0 is the best and 5.0 is the worst.

Your application is then discussed by the entire study section. Differences of opinion are discussed, and reviewers attempt to reach a general consensus. Then, each proposal is assigned a priority score by each study section member by secret ballot. SRAs will question any score differing significantly from the range discussed. The final priority score is the average of the secret ballot scores.

## Summary Statements

After the meeting, the SRA prepares a summary statement for each application. Summary statements include the reviewers prepared comments, a summary of the deliberations, an average priority score, and recommended changes in budget and administrative items, if any. The summary statement will list the reviewers participating but will not indicate which were primary reviewers or readers.

NIH mails summary statements to applicants roughly six to eight weeks after the initial review group meeting and provides this information to the IC Program Officer responsible for the application. ***It's a good idea to wait till after you receive and review your summary statement before calling your Program Officer to learn if your application is likely to be funded.***

There is an appeals process in the event that a review is seriously flawed procedurally. ***Flawed means errors in the review of your application because of conflict of interest or bias, but not because of differences in scientific judgment. If you believe that there were grievous errors, talk with your Program Officer to discuss your best course of action.***

## How Funding Is Decided

Each IC considers SBIR and STTR applications for funding based on quality as judged by the study section, on the relevance of the application to the IC's mission and on availability of funds. Some ICs set a "payline" where all applications with priority scores better (lower) than the payline are funded. **The payline is likely to vary among ICs.**

Based on these considerations, extramural program staff prepare a prioritized list of applications for consideration by an IC's SBIR and STTR secondary review group. **This review group may be an IC's Advisory Council, or may it may be a different group.** At the secondary review group meetings, which occur three times a year, members consider the prioritized list and summary statements of grant applications forwarded by the program staff. The group may also consider complaints or other information from applicants regarding the quality of the review.

Following that meeting, ICs take one of four actions:

1. The application may be approved for funding.
2. The primary responsibility for an application may be transferred for funding to another IC that agrees to fund it.
3. The application may deferred for later decision, usually at the end of the fiscal year.
4. The application is not funded, and its file is closed. See "Revising Your Application" on page 35.

## Why Your Application May Be Deferred for Later Decision

ICs receive and disperse funds by fiscal year (October 1 through September 30). Payment of too many applications following the first (September/October) or second (January/February) review meeting in the fiscal year could preclude payment of better applications later in the fiscal year. Thus, after each of the first two review meetings, ICs usually fund only applications highly likely to rank in the fundable range of all applications received for the

year. Typically, they will defer decisions for borderline applications until after the third (the final) review in May or June. If funds are still available, ICs will usually fund deferred applications in priority order.

## Success Rates

Success rate is a measure of the probability of being funded, not the probability of a successful outcome of your research. In this guide we will define the "success rate" as the number of applications funded divided by the number received, multiplied by 100. The average success rates for NIH SBIR applications from 1991 to 1995 are shown in **Figure 6**; the data are provided in **Table 5**.

The values for SBIR success rates are the average for all ICs. Success rates differ among ICs depending upon funds available and the number of applications received.

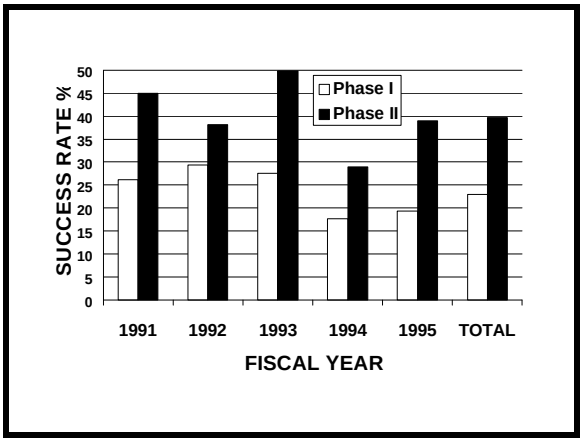


**Figure 6. SBIR Success Rate**

**Table 5. Success Rates for NIH SBIR Applications From 1991 to 1995**

| Fiscal Year | Phase I SBIRs | | | Phase II SBIRs | | | All SBIRs | | |
|---|---|---|---|---|---|---|---|---|---|
| | Review | Award | Rate | Review | Award | Rate | Review | Award | Rate |
| 1991 | 1,788 | 468 | 26.2 | 314 | 141 | 44.9 | 2,102 | 609 | 29.0 |
| 1992 | 1,842 | 541 | 29.4 | 364 | 139 | 38.2 | 2,206 | 680 | 30.8 |
| 1993 | 2,132 | 588 | 27.6 | 430 | 214 | 49.9 | 2,562 | 802 | 31.3 |
| 1994 | 2,991 | 526 | 17.6 | 464 | 134 | 28.9 | 3,455 | 660 | 19.1 |
| 1995 | 3,200 | 619 | 19.3 | 543 | 212 | 39.0 | 3,743 | 831 | 22.2 |
| Total | 11,953 | 2,742 | 22.9 | 2,116 | 841 | 39.7 | 14,069 | 3,583 | 25.5 |

**Table 6** provides a summary of SBIR awards by ICs from 1991 to 1995. Because all ICs use the same percentage of their extramural funds for SBIR grants, the largest ICs make the most SBIR awards.

***You may want to frame your application for a particular IC(s). In a cover letter accompanying your application, suggest that it receive primary assignment to your first choice. You can improve your likelihood of funding by requesting that your application receive secondary assignment to additional ICs that you believe would be interested in your***

***proposal. You may justify your choices by referring to the "Program Description and Research Topics" listed in the Omnibus Solicitations or by other reasonable criteria.***

**Table 6. Number of SBIR Awards by Institute or Center From 1991 to 1995**

| Institute or Center | Phase I SBIRs | Phase II SBIRs | All SBIRs |
|---|---|---|---|
| NCI | 607 | 143 | 750 |
| NHLBI | 348 | 123 | 471 |
| NIAID | 316 | 87 | 403 |
| NIGMS | 235 | 76 | 311 |
| NICHD | 149 | 48 | 197 |
| NIDDK | 142 | 52 | 194 |
| NINDS | 141 | 46 | 187 |
| NCRR | 113 | 26 | 139 |
| NIMH | 107 | 46 | 153 |
| NEI | 104 | 22 | 126 |
| NIA | 90 | 45 | 135 |
| NIDA | 86 | 35 | 121 |
| NIAMS | 82 | 17 | 99 |
| NIDCD | 49 | 18 | 67 |
| NIDR | 44 | 17 | 61 |
| NIEHS | 40 | 13 | 53 |
| NCHGR | 32 | 13 | 45 |
| NIAAA | 25 | 10 | 35 |
| NINR | 24 | 3 | 27 |
| NLM | 8 | 1 | 9 |
| TOTAL | 2,742 | 841 | 3,583 |

## Revising Your Application

***Be prepared to revise and resubmit your application. Competition for NIH funds has become increasingly tough. This means that getting a fundable priority score on the first try is becoming harder to do. Revising is your opportunity to address reviewers' concerns. Many applications succeed on the second or even third submission. It is key to respond to the comments and suggestions of the peer review committee. FIRST, talk with your Program Officer to review your summary statement and obtain advice. It is also wise to ask someone experienced in grantsmanship and not involved in your proposed research to review your application, summary statement, and revision plans. New NIH rules allow you to submit a maximum of two revised applications.***

Even if you respond adequately to all the criticisms in the summary statement, you are not guaranteed an award. This may happen because a summary statement is not meant to be an exhaustive critique; some problems discussed by the reviewers may not appear in it. Also, when you make changes, you run the risk of introducing new problems. Finally, membership in initial review groups is constantly changing. Your application is likely to be seen by some new reviewers who may have different views of your proposal.

**NOTE: Studies show that applications that are not funded after two revisions are not likely to be funded following further revision. Beginning with the April 1997 receipt date, NIH has adopted a policy to save time and effort of both applicants and reviewers. No more than two revisions of any NIH application will be accepted and all revised applications must be submitted within two years of the receipt date of the initial application.**

## When an Application Is Approved for Funding

If the IC approves your application for funding, you will be contacted for necessary additional information described under **Just in Time Information** on page 16. Upon satisfactory completion of all requirements, the IC sends you a “Notice of Award” with a start date for your grant. The next chapter describes this process.

# IV. YOU HAVE BEEN APPROVED FOR AN AWARD

Congratulations are in order when you learn that you will be receiving an SBIR or STTR award from NIH. What's next?

If it is your first NIH SBIR or STTR award, you will receive a "Welcome Wagon" memorandum with lots of important information on what to do. Read it carefully and note the following tips.

## Documentation

NIH staff will check for documentation that shows you meet basic SBIR or STTR requirements. Further, there are two items NIH absolutely **must** have before it can issue an award: the animal welfare assurance and protection of human subjects assurance. If human or animal subjects are involved, you must obtain approval from the NIH Office of Protection from Research Risks (OPRR). ***It is a good idea to begin working on these items when you learn that your score is in a range that may be fundable (e.g., under 225, but talk to your Program Officer).***

- **Human Subjects**

To obtain information concerning a human subjects assurance, contact OPRR at:

Division of Human Subject Protection
Assurance Staff
Office for Protection from Research Risks, OER, NIH
6100 Executive Boulevard MSC 7507
Suite 3B01
Rockville, MD 20892-7507
(301) 496-7005

To assist institutional review board (IRB) members, researchers, and institutional administrators, OPRR produced a 1993 publication entitled, *Protecting Human Research Subjects: Institutional Review Board Guidebook*. It is available for $31 from the U.S. Government Printing Office (202) 512-1800; stock no. 017-040-00525-3.

In addition, OPRR provides an instructional videotape on the protection of human subjects. This videotape, available free of charge, contains three programs:

1. Evolving Concern, Protection for Human Subjects
2. Balancing Society's Mandates, IRB Review Criteria
3. The Belmont Report, Basic Ethical Principles and their Application

To obtain a copy of the videotape, contact:

Education Program Coordinator
Division of Human Subject Protection
Office for Protection from Research Risks, OER, NIH
6100 Executive Boulevard MSC 7507
Suite 3B01
Rockville, MD 20892-7507
(301) 496-7005

- **Animals in Research**

To obtain information regarding animal welfare assurance requirements or to request the publication *Public Health Service Policy on Humane Care and Use of Laboratory Animals*, contact:

Division of Animal Welfare Assurance
Office for Protection from Research Risks, OER, NIH
6100 Executive Boulevard MSC 7507
Suite 3B01
Bethesda, MD 20892-7507
(301) 496-7163

## What You Can and Cannot Pay for on a Grant

Your grant can pay for the actual costs of research proposed in the grant application (direct costs) plus an appropriate percentage of the allowed amount of your organization's other expenses (indirect costs) that are not specifically identified with a project.

***Good news! You may not have to worry about indirect costs for your first Phase I SBIR or STTR grant. However, eventually you will have to separate your expenses into direct and indirect costs and establish an "indirect cost rate" through a formal agreement between your organization and the Federal Government. Instructions on indirect cost determinations are in the SBIR and STTR solicitations, but you will probably want to leave the details to an accountant who is knowledgeable about negotiating Federal indirect cost rates.***

***A good time to select your accountant is BEFORE you have to submit your "just in time" budget.***

The allowability, allocability, reasonableness, and necessity of direct and indirect costs that may be charged to PHS grants and cooperative agreements are outlined in FAR 48 Subpart 31.2. A copy of this document may be obtained from the NIH Office of Contracts and Grants

Management (301) 496-2444 or on the Internet at http://www.gsa.gov/far/. In addition, you may want a copy OMB Circular A-133, which describes administrative standards and audit requirements for organizations receiving Federal assistance.

You may obtain more information on indirect rates from:

Chief, Financial Advisory Services Branch
Office of Contracts and Grants Management, NIH
6100 Executive Boulevard, Room 6B05
Bethesda, MD 20982-7540
(301) 496-4401

***You will probably want to ask an accounting firm familiar with Federal funding to help you understand and comply with regulations. Also, you may need help from them to determine the best method to address tax issues related to receipt of grant funds.***

## Financial Review

***NIH is more likely to perform a financial review if the firm has not had previous Federal funding. Even so, information may be requested such as the previous year's statement of assets and liabilities (balance sheet), how the company handles its payroll and purchasing, and it's accounting methods. It is helpful to provide NIH with the name of your accounting firm.***

***Companies with heavy liabilities raise concerns by NIH grants administrators. NIH looks at the firm's asset to liability ratio, calculated by dividing assets by liabilities. Here's how the ratios are treated: 2:1 is desirable; 1:1 is acceptable, less than 1:1 indicates insolvency.***

***If a company's ratio is less than 1:1, NIH may request a cash flow forecast covering the first budget period and evidence of a bank line of credit that can cover capital shortages. Also, if a company lists unbilled accounts receivable under its assets, NIH may request more detailed information.***

***NIH will also divide the company's assets excluding inventory and prepaid expenses by its liabilities as another means of assessing solvency. A ratio of less than 1:1 indicates cash flow problems.***

***What if you are a new company with little or no assets or liabilities? This is not necessarily a problem. Showing a bank line of credit often will be enough to ensure that an academician setting up a new company has the means to pursue the research.***

## Terms and Conditions of Award

Acceptance of the award means that you agree to be bound by its "Terms and Conditions." To learn more about these, request a copy of the Public Health Service Grants Policy Statement (GPS), also on the Internet at gopher://gopher.nih.gov:70/11/res/PHSGPS. The current GPS was issued April 1, 1994, and an interim update on February 15, 1995. Free copies may be obtained by calling the NIH grants information office at (301) 435-0714.

## Getting Paid

Payments are made through the Payment Management System (PMS). To get paid, you first must have an Employer Identification Number (EIN), which you obtain from the U.S. Internal Revenue Service. Your social security number will not suffice to move funds into your institution's bank account.

Next, you will be assigned a 12-digit EIN for payment and accounting purposes. That number is an expansion of the 9-digit EIN assigned by the Internal Revenue Service. To get more information and obtain your expanded number, contact the IC of your first grant. You will retain the same EIN for other grants.

As a grantee, your organization will be paid by electronic transfer of funds directly into its bank account as you report incurred expenses.

## Accounting for Your Funds

You will submit a Financial Status Report (FSR) on Standard Form (SF) 269 or 269A to report expenditures and remaining funds at the end of Phase I and Phase II. You may be asked to submit an FSR at the end of the first year of Phase II for Fast-Track SBIR grants. For information contact:

National Institutes of Health
DFM/FAAB/Grants Section
Building 31, Room B1B11 MSC 2052
Bethesda, MD 20892-2052
(301) 496-5287

Alternatively, NIH has established a system for the electronic transmittal of financial status reports that allows participants to submit FSRs electronically. You can contact the office listed above to learn how to use this system.

***Be aware that you may be audited***. Audit requirements for Federal award recipients are defined in OMB Circular A-133, except that recipients of SBIR Phase I awards receiving no more than $100,000 in cumulative Federal awards **in a given year** are exempt. However,

your organization must have all necessary records available for review by NIH should NIH elect to audit you. For technical assistance pertaining to A-133, call the HHS regional office in Kansas City on (800) 732-0679 or (816) 374-6714.

## Progress Report

All NIH awards require an annual progress report, which usually is submitted with the application for continuation support. You will usually include your Phase I progress report with your application for Phase II funding. However, if you will not be submitting a Phase II application, or if you will be submitting a Phase II application more than 90 days after the end of Phase I, you will need to submit a final progress report within 90 days after the termination of the Phase I grant.

## No-Cost Time Extension to Complete Research

Sometimes you need additional time to complete your research. First, talk with your Program Officer. Then, submit a request in writing to the Grants Management Specialist in charge of your grant. The name of your Specialist is listed on your Notice of Grant Award.

You must explain why an extension is needed, identify the specific research that needs to be completed, the reason it is delayed, and the amount of unexpended funds to be used. The request must be signed by both the Principal Investigator and your company's business office. ***Refer to or use the budget page form from a grant application to help you provide the necessary budget information.***

**Note:** Unless specifically excluded from expanded authorities, Phase II grants do not require prior approval of a no-cost extension but require that NIH be notified 90 days prior to the original project period end dates.

## Reasons You Could Lose Your Grant

Though it doesn't happen every day, a company may lose a small business grant if:

- The company goes out of business or appears to be insolvent.
- The PI leaves and there is no suitable replacement.
- The PI takes the grant to another company (both companies must agree).

If the business no longer qualifies as a small business (e.g., purchase by a larger non-qualifying company), the award may be retained, but a Phase II application may not be submitted following completion of a Phase I. ICs may differ in processing these cases, e.g., NIAID converts a no-longer eligible SBIR or STTR grant to a regular research grant (R01).

# More Information – Electronically

- **Modem Connections**

The NIH Grant Line is an electronic information service (bulletin board system) that includes files containing the *NIH Guide for Grants and Contracts*, NIH extramural program guidelines, organization listings from the NIH Telephone Directory, and other information of interest to applicants.

To connect to the NIH Grant Line with a modem: (1) Configure your terminal emulator as: 1200 or 2400 baud, even parity, 7 data bits, 1 stop bit, half duplex. (2) Using the procedure specified for your communications software, dial 1/301/402-2221. When you get a response indicating that you have been connected, type ,Gen1 (the comma is required) and press Enter. You will be prompted by the NIH system for "Initials?". Type BB5 and press Enter. You will then be prompted for "Account?". Type CCS2 and press Enter.

For additional information, contact the Division of Research Grants, Special Projects Office, at (301) 435-0692.

- **Electronic Access To Grant-Related Resources Over The Internet**

You can electronically access numerous grant-related resources such as the *PHS Grants Policy Statement*, *NIH Guide to Grants and Contracts*, NIH Telephone Directory and other grant resources at one of the following Internet addresses:

**gopher.nih.gov** (NIH gopher)
**http://www.nih.gov** (NIH Home Page)

These addresses can be reached through software clients such as Gopher for Gopher servers and Mosaic, Netscape, or other browsers for World Wide Web (WWW) servers. Many of the 21 NIH institutes, centers, and divisions also have gopher and WWW addresses.